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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,592	08/13/2001	Jess Paul Fuller	V0005/7097	9457
28120	7590	01/30/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,592

Applicant(s)

FULLER ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 34, 35, 37-39, 41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 34, 35, 37-39, 41 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/29/15/16/102
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment of 10/20/03 amended claims 1, 37-39, 41 and 43, and canceled claims 28-33, 36, 40, 42 and 44-161.

Document BA on form PTO-1449 of 10/20/03 has been lined through since the document was previously listed on form PTO-892 of 4/22/03.

5 Claims examined on the merits are 1-27, 34, 35, 37-39, 41 and 43 which are all claims in the application.

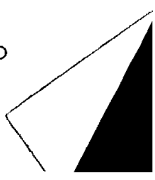
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

10 Claims 5, 7, 9, 15, 24, 34, 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 Reciting "preferably" in claims 5, 7, 9, 15, 37 and 38 makes unclear as to whether the preferred conditions are to be patentably limiting. Reciting preferred conditions that are not to be patentably limiting confuses and beclouds the metes and bounds that are to be patentably limiting. It is suggested that preferred conditions be deleted where required. If desired, the deleted conditions may be
20 recited in dependent claims further limiting the claims in which the condition is deleted. For example, a claim can be dependent on claim 5 requiring the filler to be crystalline.

In claim 24, "such as" makes the claim unclear for the same type of reason set forth above in regard to "preferably". If "glass" is to



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be claimed, a claim can be dependent on claim 24 requiring the inert substance of claim 24 to be glass.

Claim 34 is unclear how it further limits claim 1 since carrying out the steps of claim 1 to produce a porous silicone rubber would inherently require the filler to be dispersed and be substantially porous as in claim 34. Additionally, there is not clear antecedent basis for "the structured silicone rubber" in line 2 of claim 34 since "structured silicone rubber" has been deleted from claim 1.

Claim Rejections - 35 USC § 103

10 Claims 1-27, 34, 35, 37-39, 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al (5,998,185) or WO 94/16058 (newly applied) in view of Williams et al (6,245,537 B1) (newly applied) and Mikos et al (5,514,378) (newly applied) and Fuller (WO 97/08291).

15 The claims are drawn to producing a silicone rubber article having a structure adapted for growth of cells or living tissue by mixing a sacrificial filler with a silicone rubber precursor, curing the resultant mixture at a temperature below 180°C and removing the sacrificial filler to form a porous silicone rubber.

20 Fuller et al ('185) disclose producing a silicone rubber support structure for cells that is porous such as by being a sponge or foam (col 1, lines 35-66). The porosity may be controlled by including an additive during formation of the silicone rubber structure (col 6, lines 33-35). Metal powders may be added to provide a dense structure

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(col 1, lines 53-55 and col 6, lines 45-46). Substances may be added to give the structure particular surface properties such as by providing agents on the surface that facilitate retention of cells (col 3, lines 35-40). Fuller et al (WO) contains the same disclosure
5 as Fuller et al ('185).

Williams et al disclose producing a porous polymeric material for tissue engineering (paragraph bridging cols 22 and 23). Pores can be introduced into the polymeric material such as by using foaming agents, processing of fibers into woven or non-woven structures, phase
10 separation and leaching (col 23, lines 6-22). Leaching involves dispersing solid particles such as a salt within the polymer and dissolving the particles out of the polymer with a solvent that does not dissolve the polymer. The particles may be dispersed in a solution of the polymer followed by evaporating solvent, and
15 dissolving the particles (col 14, lines 10-26). Alternatively, the polymer may be blended with the particles, melt processed into an appropriate mold, and the particles leached from the polymer (col 14, lines 28-31).

Mikos et al disclose producing a porous three-dimensional matrix
20 as a cell support for transplantation and implantation of cells (col 1, lines 5-10 and col 2, line 65 to col 3, line 4). Pores are formed using the particulate-leaching technique (col 3, lines 6-25 and col 4, line 55 to col 7, line 43) of adding particles such as salt particles to a solution of the polymer, evaporating solvent to form the matrix

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and dissolving the particles out of the matrix by immersing the matrix in water.

Fuller discloses (page 3, line 11 to page 4, line 20) providing a textured (col 3, line 19) growth surface for cells by coating the
5 inside surface of a growth bottle with silicone rubber, adding salt particles to the silicone rubber coating while still liquid, polymerizing the coating to form a solid layer studded (page 3, line 13) with the salt particles, and removing the salt particles by dissolution in water to leave a surface porous layer (page 4, lines
10 15-16) exhibiting a cratered or micro-cupellated structure.

When using a porous silicone rubber support structure for cells as disclosed by Fuller et al ('185) or (WO), it would have been obvious to form the porous support structure by adding filler particles to a silicone rubber precursor, curing and removing the
15 filler particles as suggested by Williams et al disclosing leaching added solid particles as an alternative to using foaming agents (col 23, lines 7-15) and Mikos et al disclosing using the particulate-leaching technique to produce a porous polymer matrix for use as a cell support and Fuller disclosing using this type of technique to
20 provide a silicone rubber coating with a textured surface that is surface porous and adheres cells. The disclosure by Fuller et al of controlling porosity by including an additive during formation of the silicone rubber structure (col 6, lines 33-35) would have suggested that adding solid particles and leaching will be an acceptable way of

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forming silicone rubber containing pores. Fuller (page 8, line 26) would have suggested curing at below 180°C by disclosing curing at 70°C. No unexpected result is seen in using the particulate-leaching technique of the secondary references to form the porous silicone rubber cell support structure of Fuller et al. The conditions of the dependent claims are disclosed by the references or would have been obvious from the conditions disclosed. The silicone rubber of Fuller et al can be cured at room temperature as in claim 2 and is non-toxic as in claim 3. The secondary references disclose salts as in claims 11-14, 16 and 17, and removing the salts by dissolution as in claim 15. The salts of the references will not interact as in claim 4. Selecting specific forms of the salt such as granular, crystalline or amorphous as in claims 5 and 6 would have been a matter of obvious choice. Grinding or milling the filler as in claims 7, 8 and 13 would have been obvious to obtain a preferred optimum size as in claim 9 which is suggested by the size of fillers used by the secondary references. Wet-milling as in claims 8 and 14 is a well known procedure for obtaining a preferred particle size. Fuller et al suggest agents on the surface that facilitate retention of cells, and Williams et al suggest providing functional -OH groups as in claim 18 (col 8, line 45) and bombardment with electrons as in claim 19 (col 8, lines 25-47). The additive of claims 20-24 is suggested by Fuller et al adding density control agents such as metal powder. Fuller discloses producing a textured surface as in claims 25-27. Dispersing and being porous as in claim 34 is involved in the particulate-

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leaching technique. The pores of the structure Fuller et al provide cell attachment sites as in claim 35 and the structure of Fuller et al can be shaped as in claim 37. The pore size of claim 38 would have been obvious from pore sizes disclosed by the references. Fuller et al suggest a shaped structure having a desired size, and cutting as in claim 39 would have been an obvious way to obtain a desired shape or size. Combining the teachings of the references as set forth above would have inherently resulted in a silicone rubber and device or apparatus as required by claims 41 and 43.

Response to Arguments

Applicants urge that the claims are now drawn to producing a silicone rubber article by the method of canceled claim 26. However, Fuller et al disclose silicone rubber articles. Producing the articles as required by claim 36 would have been obvious in view of the secondary references. Using the particulate-leaching technique that is well known for producing porous polymer articles to produce the porous silicone rubber article of Fuller et al would have been well within the ordinary skill of the art. No unexpected or unobvious result is seen in producing the porous silicone rubber of Fuller et al using the particulate-leaching technique.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41 and 43 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Fuller et al (WO 94/16058) or ('185), respectively.

The claims are drawn to a silicone rubber or biomedical device or apparatus produced by the method of claim 1.

Fuller et al (WO) and ('185) are described above.

The porous silicone rubber of claim 40 and device of claim 43 can be the same as the porous silicone rubber support structure of Fuller et al (WO) or ('185). The process of claim 1 does not result in a different support structure since the process can result in a silicone rubber having the same porosity as the structure of Fuller et al.

Double Patenting

Claims 1-27, 34, 35, 37-39, 41 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,998,185 in view of Williams et al and Mikos et al and Fuller.

It would have been obvious to produce the silicone rubber support structure of the claims of the patent using the particulate-leaching

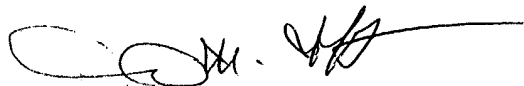
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technique taught by Williams et al, Mikos et al and Fuller since this technique is a well known for producing porous polymers, and claim 24 of the patent requires controlling porosity by including an additive during formation of the structure.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
10 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose
15 telephone number is 703-308-0196.



David M. Naff
Primary Examiner
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